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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,117	06/13/2001	Johan Wanselin	003300-794	3882

7590 07/13/2004
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EXAMINER

CHORBAJI, MONZER R

ART UNIT PAPER NUMBER

1744

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,117	Applicant(s) WANSELIN ET AL.	
	Examiner MONZER R CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This non-final office action is in response to the amendment received on 04/30/2004

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Regarding claim 1, line 2, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). The same applies to claim 13, line 3.
3. Regarding claim 3, line 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The same applies to claims 4 and 16.
4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3; applicant recites the limitation "to be mounted to the remaining sterilization device". What does the applicant mean by "remaining"? Does the applicant mean that the device and the chamber form one entity? Clarification is needed to understand the meaning of claim 1.

In claim 1, lines 2-4; applicant recites the phrase "said sterilization chamber being arranged to be mounted to the remaining sterilization device and to partly define a

sterilization enclosure in the sterilization device such that". This phrase is not considered as a positive limitation. Proper rewording of this phrase is needed in claim 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5-6, 12-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Spence (U.S.P.N. 4,919,888).

With respect to claim 1, Spence teaches a sterilization chamber (figure 1, 12 and 14 or 10) for use in a sterilization device (col.6, lines 18-21) such that the sterilization chamber encloses goods to be sterilized (col.6, lines 34-37) and has a self supported structure being essentially made of a polymeric material (col.4, lines 30-36). In addition, the chamber (10) is put into position (i.e., mounted) within the remaining sterilization device (col.6, lines 18-21). The word mounted is interpreted as "put into position" as shown on page 760 of the 10th edition of Merriam-Webster's Collegiate Dictionary. The limitation "remaining" is considered as the following: the chamber is one part and the device is the remaining part such that the chamber is inserted or mounted into the remaining part, i.e., device for sterilization. Also, the chamber of Spence does fill part of the inside space of the device thus partly defining a sterilization enclosure within the device.

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With respect to claims 2, 5-6, 12-13, and 15, Spence teaches the following:
chamber is made of an injection-mouldable material that is essentially a polyamide material (col.4, lines 36-37 and col.4, line 31), chamber is made of a composite material (col.4, line 31), chamber is essentially manufactured in one continuous piece (col.4, lines 35-37), inlets and outlets for steam are integrally formed in the chamber (figure 1, 36. side walls act as integral steam inlets and outlets until the chamber is fully sealed), and a sterilization device being provided with a sterilization chamber intended for a sterilization process to be performed (col.6, lines 18-24).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 3-4, 7-9, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence (U.S.P.N. 4,919,888) in view of Quehl (U.S.P.N. 4,165,404).

The teachings of Spence have previously been set forth with regard to claims 1-2, 5-6, 12-13, and 15. With respect to claims 17-18, Spence teaches that chamber is made of an injection-mouldable material that is essentially a polyamide material (col.4, lines 36-37 and col.4, line 31). However, with respect to claims 3-4, 7-9, and 16, Spence fails to teach the following: the use of a reinforcement material such as rowing weave, and the use of carbon fiber and a concatenating polymer material such as an epoxy material. However, with regard to claims 3-4, 7-9, and 16, Quehl teaches the following: the use of a reinforcement material such as rowing weave (col.2, lines 11-14 and line 45) arranged around the injection mouldable material (col.7, lines 24-27 and lines 48-50), and the use of carbon fiber (col.2, line 44) and a concatenating polymer material such as an epoxy material (col.6, lines 10-12), the use of glass fiber (col.2, line 44) and a concatenating polymer material (col.6, lines 10-12). Thus, it would have been obvious to one having ordinary skill in the art to modify the chamber of Spence to include glass or carbon fibers because of their desirable physical properties (Quehl, col.2, lines 47-48).

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spence (U.S.P.N. 4,919,888) in view of Quehl (U.S.P.N. 4,165,404) and further in view of Limbacher et al (U.S.P.N. 5,837,181).

With respect to claim 10, both Spence and Quehl fail to teach the use of specific types of concatenating polymers provided in such a claim. However, Limbacher et al teaches the use of polyvinyl alcohol fibers (col.5, lines 25-26). Thus, it would have been obvious to one having ordinary skill in the art to modify the sterilization chamber of Spence to include polyvinyl alcohol since such a fiber is known to have a high modulus (Limbacher et al., col.5, lines 25-26).

12. Claims 11, 14, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence (U.S.P.N. 4,919,888) in view of Houston et al (U.S.P.N. 5,894,014).

With respect to claims 11, 14, and 19-20, Spence fails to disclose that the chamber is releasably mountable in the sterilization device and the chamber is provided with a pair of integrally formed tracks, in which a sealing chamber door may be slidably mounted. However, Houston et al teaches that the chamber (12) is releasably mountable (12 is fastened or secured to 28) in the sterilization device (10) and the chamber (12) is provided with a pair of integrally formed tracks (36), in which a sealing chamber door (30) may be slidably mounted (col.2, lines 62-65). Thus, it would have been obvious to one having ordinary skill in the art to modify the chamber of Spence to include a pair of integrally formed tracks in order to provide for vertical travel of the sealing chamber door (Houston et al, col.2, lines 64-65).

Response to Arguments

13. Applicant's arguments filed 04/30/2004 have been fully considered but they are not persuasive.

On page 6 of the response, applicant argues that, "the container in Spence is just placed in a sterilization device for a sterilizing process and hence, does not define a sterilization chamber for use in a sterilization device or a sterilization enclosure in the sterilization device". The examiner disagrees. The chamber (10) of Spence defines a space within which medical articles are sterilized. It is a chamber because it is a sealed enclosure (abstract, lines 1-8). The chamber is mounted within the sterilization device. The meaning of "mounted" has previously been explained above.

On page 6 of the response, applicant argues that, "Hence, unlike the present invention, the container of Spence is not pressurized and exposed to the same pressure as a pressure chamber, i.e., sterilization chamber, of a sterilization device". The examiner disagrees. Steam is generated within the sterilization device that is used to sterilize the contents of chamber (10) as explained in col.6, lines 18-45 and in col.3, lines 36-41. Thus, the chamber (10) of Spence is pressurized and is exposed to the same pressure as the pressure generated within the sterilization device in order to sterilize its contents. In addition, the instant claims do not recite pressurization.

On page 7 of the response, applicant argues that, "The Spence container is, at the utmost, exposed to a pressure on the outside of the container when it is sealed". The examiner disagrees. The chamber (10) of Spence contains filter means, which allow the entry and exit of steam (col.3, lines 36-41) in order to sterilize its contents. As

a result, the internal of the chamber is pressurized to the same pressure as the pressure within the sterilization device.

On page 7 of the response, applicant argues that, "Third, in contrast to Spence, the sterilization chamber in the present invention is arranged to be mounted to the remaining sterilization device and to partly define a sterilization enclosure in the sterilization device. The container in Spence does not form part of the sterilization device". The examiner disagrees. With respect to the "mounted" and "to partly define a sterilization enclosure in the sterilization device", the scope and meaning of such limitations have previously been addressed above in claim 1. In addition, the Spence chamber (10) does form part of the device when mounted within it by forming a sealed enclosure where sterilization of medical equipments occurs (col.6, lines 19-21). Further, such a limitation is not recited in the instant claims.

Conclusion

14. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. The Nichols (U.S.P.N. 4,617,178) discloses a polymeric sterilization chamber for use in a sterilization device.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 872-9306.

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744
07/09/2004

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